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July 23, 2001

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

APPLICATION FOR EXEMPTION

Subject: Cimetidine Tablets, 200 mg
ANDA 75-285

Docket No. 98N-0337 APPLICATION FOR EXEMPTION

On July 19, 2001, Perrigo requested an exemption from 21 CFR 201.66(c) and (d) in the form of a temporary deferral of the implementation of the requirements of this regulation. At this time we are replacing page 1 of the cover letter to correct the ANDA number to **75-285** from 72-285. Please find enclosed 3 copies (1 original plus 2 copies) of the application.

If you have any further questions or comments, please contact Brian Schuster at 616-673-9745, or by fax at 616-673-7655.

Sincerely,

Tricia Pasek

Tricia Pasek
Administrative Assistant
Regulatory Affairs

98N-0337

CR 1

515 Eastern Avenue
Allegan, Michigan 49010
(616) 673-8451

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Statement of Purpose

Pursuant to 21 CFR 201.66(e), Perrigo requests an exemption from 21 CFR 201.66(c) and (d) in the form of a temporary deferral of the implementation of the requirements of this regulation. This deferral is requested because there is not currently approved labeling in the Drug Facts format for the reference listed drug available to the Perrigo Company. The exemption would apply to all current and future SKUs of the drug product.

The reference listed drug for this ANDA is Tagamet HB® 200 (NDA 20-238).

Background of the Request

From the time that the final rule was issued in 1999, it has been the understanding of the Perrigo Company, through several contacts with the Office of Generic Drugs, that the Agency would not approve ANDA labeling formatted according to the requirements described in 21 CFR 201.66 until approved reference listed drug labeling similarly formatted was available. Perrigo further understands, based on these contacts, that in the absence of approved reference listed drug labeling in drug facts format, ANDA labeling could not be converted regardless of the May 2002 deadline.

We believe that it is the Office of Generic Drugs' position that Drug Facts and non-Drug Facts format labeling may not be 'the same' as required by the Food Drug and Cosmetic Act under part 505 (j)(2)(A), and in fact, that the ANDA holder cannot know if the labeling will be 'the same' until the reference listed drug labeling is available for comparison. Therefore, in order to ensure continuing compliance with both the statue and the regulation, a temporary deferral of the implementation date is required until approved reference listed drug labeling is available in Drug Facts format.

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In a letter from Dr. Charles Ganley to the Consumer Healthcare Products Association dated August 9, 1999, it was recommended that ANDA holders submit a request for deferral in those cases where the reference listed drug has not received approval for labeling in the Drug Facts format in sufficient time to allow conversion of the ANDA product labeling by the regulatory compliance date.

"Templates" for Drug Facts Labeling
The Office of Generic Drugs has published in a February 2001 draft guidance, certain templates for drug facts labeling of particular drugs, and has since published additional templates for products for which there is not approved reference listed drug (RLD) labeling in Drug Facts format. The February 2001 draft guidance also made reference to the potential for ANDA applicants to submit changes to implement Drug Facts labeling in the absence of an approved reference listed drug in this format.

Our discussions as late as July 2001 with OGD representatives have verified that the presence of a published template does not confer any special status to a drug product in the absence of approved RLD labeling. OGD will not grant approval for a supplement to implement drug facts labeling for an OTC ANDA product before the approval of the RLD in the same format. Further, since labeling in drug facts format and non-drug facts format is not considered to be "the same", ANDA holders may not implement Drug Facts format labeling by way of an annual report. The potential finalization date and content of the February 2001 draft guidance is unknown.

Length of the Deferral Request
Due to the large number of store-brand private labels maintained by Perrigo for each ANDA OTC drug product, converting the labeling to Drug Facts format requires significant time and resources. For any drug product for which Drug Facts format labeling is not available as of the date of this letter, Perrigo is submitting a request for a temporary deferral of implementation.

At the time that approved Drug Facts format labeling becomes available for each RLD, Perrigo will immediately act to file a Changes Being Effected Supplement for approval of the new labeling in the relevant ANDA. The product will then be entered into our labeling conversion schedule. Due the length of time required to prepare labeling, submit a CBE supplement, and finally convert the labeling of a product, we anticipate that conversion for a particular product can be accomplished within approximately six months from the approval of the labeling supplement or twelve months from when the RLD labeling is first approved and available to Perrigo in Drug Facts format.

If the reference listed drug for this ANDA has approved labeling available in Drug Facts format by the compliance date of May 2002, then this deferral is not anticipated to be required beyond May 2003.

If there are any questions concerning this request, please contact me by phone at (616) 673-9745 or fax at (616) 673-7655. Thank you for your attention to this matter.

Sincerely,

L. PERRIGO COMPANY

Brian Schuster
Manager, ANDA Submissions

CC:
Gary Buehler, Director
Office of Generic Drugs
FDA/CDER
Metro Park North II
7500 Standish Place, Room 150
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